according to Regulation (EC) No 1907/2006 (REACH) as amended

# Monoclonal or polyclonal antibodies, proteins (including lyophilized)

Creation date 21st July 2023 Revision no.

Revision date Version

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

**Product identifier** Monoclonal or polyclonal antibodies, proteins (including

lyophilized)

Substance / mixture mixture

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

### Mixture's intended use

Monoclonal or polyclonal antibody, single antibody labeled with fluorochrome or cocktail of fluorescently labeled antibodies and proteins (including lyophilized) containing sodium azide as a preservative.

# The use descriptors

SU 24 Scientific research and development

PC 21 Laboratory chemicals PROC 15 Use as laboratory reagent

## Mixture uses advised against

The product should not be used in ways other than those referred in Section 1.

#### 1.3. Details of the supplier of the safety data sheet

#### Manufacturer

Phone

Name or trade name EXBIO Praha, a.s.

Address Nad Safinou II / 341, Vestec, 25250

> Czech Republic +420261090666 orders@exbio.cz

F-mail Web address www.exbio.cz

#### Competent person responsible for the safety data sheet

EXBIO Praha, a.s. Name orders@exbio.cz F-mail

#### 1.4. **Emergency telephone number**

National Health Service (NHS) 111

National poisoning information centre Scotland, NHS 24: 111

# **SECTION 2: Hazards identification**

### Classification of the substance or mixture

# Classification of the mixture in accordance with Regulation (EC) No 1272/2008

The mixture is not classified as dangerous according to Regulation (EC) No 1272/2008.

Full text of all classifications and hazard statements is given in the section 16.

#### 2.2. **Label elements**

none

# 2.3.

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Mixture does not contain any substance meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended.

according to Regulation (EC) No 1907/2006 (REACH) as amended

# Monoclonal or polyclonal antibodies, proteins (including lyophilized)

Creation date 21st July 2023 Revision no.

Revision date Version 1

## **SECTION 3: Composition/information on ingredients**

#### **Mixtures**

Mixture contains these hazardous substances and substances with the highest permissible concentration in the working environment

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
Index: 011-004-00-7 CAS: 26628-22-8 EC: 247-852-1	sodium azide	,	Acute Tox. 2, H300+H330 Acute Tox. 1, H310 STOT RE 2, H373 (ingestion) Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1) EUH032	1

#### **Notes**

A substance for which exposure limits are set.

Full text of all classifications and hazard statements is given in the section 16.

#### **SECTION 4: First aid measures**

#### **Description of first aid measures** 4.1.

Take care of your own safety. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet.

## If inhaled

Terminate the exposure immediately; move the affected person to fresh air.

#### If on skin

Remove contaminated clothes.

# If in eves

Rinse eyes immediately with a flow of running water, open the eyelids (also using force if needed); remove contact lenses immediately if worn by the affected person.

Rinse out the mouth with clean water. In the event of issues, find medical help.

#### 4.2. Most important symptoms and effects, both acute and delayed

Possible irritation of airways, cough, headache.

# If on skin

Not expected.

# If in eyes

Possible irritation.

### If swallowed

Nausea, stomach pain, vomiting, diarrhoea.

#### 4.3. Indication of any immediate medical attention and special treatment needed

Symptomatic treatment.

# **SECTION 5: Firefighting measures**

#### 5.1. **Extinguishing media**

# Suitable extinguishing media

Alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist.

# Unsuitable extinguishing media

Water - full jet.

#### 5.2. Special hazards arising from the substance or mixture

In the event of fire, carbon monoxide, carbon dioxide and other toxic gases may arise. Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

#### 5.3. Advice for firefighters

Self-Contained Breathing Apparatus (SCBA) with chemical resistant gloves. Use a self-contained breathing apparatus and full-body protective clothing.

according to Regulation (EC) No 1907/2006 (REACH) as amended

# Monoclonal or polyclonal antibodies, proteins (including lyophilized)

Creation date 21st July 2023 Revision no.

Revision date Version

#### **SECTION 6: Accidental release measures**

## 6.1. Personal precautions, protective equipment and emergency procedures

Follow the instructions in the Sections 7 and 8.

## 6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water.

## 6.3. Methods and material for containment and cleaning up

Spilled product should be covered with suitable (non-flammable) absorbing material (sand, diatomaceous earth, earth and other suitable absorption materials); to be contained in well closed containers and removed as per the Section 13.

#### 6.4. Reference to other sections

See the Section 7, 8 and 13.

### **SECTION 7: Handling and storage**

#### 7.1. Precautions for safe handling

Prevent formation of gases and vapours in concentrations exceeding the occupational exposure limits. Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection.

### 7.2. Conditions for safe storage, including any incompatibilities

Store in tightly closed containers in cold, dry and well ventilated areas designated for this purpose.

#### 7.3. Specific end use(s)

Monoclonal or polyclonal antibodies, proteins (including lyophilized)

#### **SECTION 8: Exposure controls/personal protection**

#### 8.1. Control parameters

The mixture contains substances for which occupational exposure limits are set.

# **United Kingdom**

# EH40/2005 Workplace exposure limits (Fourth Edition 2020)

1

Substance name (component)	Туре	Value	Note
	WEL 8h	0,1 mg/m³	Can be absorbed through the skin. The assigned substances are those for which there are
sodium azide (as NaN3) (CAS: 26628-22-8)	WEL 15min	0,3 mg/m³	concerns that dermal absorption will lead to systemic toxicity.

# 8.2. Exposure controls

Do not eat, drink and smoke during work. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest.

# Eye/face protection

Protective goggles.

# Skin protection

Hand protection: Protective gloves resistant to the product.

# **Respiratory protection**

In case of inadequate ventilation wear respiratory protection.

### Thermal hazard

Not available.

# **Environmental exposure controls**

Observe usual measures for protection of the environment, see Section 6.2.

according to Regulation (EC) No 1907/2006 (REACH) as amended

# Monoclonal or polyclonal antibodies, proteins (including lyophilized)

1

Creation date 21st July 2023 Revision no.
Revision date Version

#### **SECTION 9: Physical and chemical properties**

#### 9.1. Information on basic physical and chemical properties

Appearance

physical state liquid at 20 °C color not available

Odour without fragrance pH data not available

Melting point/freezing point data not available

Initial boiling point and boiling range 100 °C

Flash point data not available Flammability (solid, gas) data not available

Upper/lower flammability or explosive limits

explosive limits data not available Vapour pressure data not available

Solubility(ies)

solubility in water soluble

Partition coefficient: n-octanol/water data not available
Auto-ignition temperature data not available
Decomposition temperature data not available

Viscosity

Kinematic viscosity data not available Density 1 g/cm³ at 20 °C

#### 9.2. Other information

not available

# **SECTION 10: Stability and reactivity**

### 10.1. Reactivity

The mixture is not reactive under normal conditions of use and storage. Sodium azide can react with metals contained in sewage to form lead or copper azide, which can explode on impact. When reacting with acids, sodium azide can release highly toxic hydrogen azide acid / hydrogen azide gas.

# 10.2. Chemical stability

The product is stable under normal conditions.

# 10.3. Possibility of hazardous reactions

Sodium azide can react with metals contained in sewage to form lead or copper azide, which can explode on impact.

# 10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost.

# 10.5. Incompatible materials

Protect against strong acids, bases and oxidizing agents.

# 10.6. Hazardous decomposition products

Not developed under normal uses. Dangerous outcomes such as carbon monoxide and carbon dioxide are formed at high temperature and in fire.

# **SECTION 11: Toxicological information**

# 11.1. Information on toxicological effects

Inhalation of solvent vapors above values exceeding exposure limits for working environment may result in acute inhalation poisoning, depending on the level of concentration and exposure time. No toxicological data is available for the mixture.

according to Regulation (EC) No 1907/2006 (REACH) as amended

# Monoclonal or polyclonal antibodies, proteins (including lyophilized)

Creation date 21st July 2023 Revision no.
Revision date Version

version version

#### **Acute toxicity**

Based on available data the classification criteria are not met.

sodium azide					
Route of exposure	Parameter	Value	Exposure time	Species	Sex
Oral	LD50	27 mg/kg		Rat (Rattus norvegicus)	
Dermal	LD <sub>50</sub>	20 mg/kg		Rabbit	
Inhalation	LC50	0.054 mg/l	4 hours	Rat (Rattus norvegicus)	

1

#### Skin corrosion/irritation

Based on available data the classification criteria are not met.

## Serious eye damage/irritation

Based on available data the classification criteria are not met.

## Respiratory or skin sensitisation

Based on available data the classification criteria are not met.

#### Germ cell mutagenicity

Based on available data the classification criteria are not met.

#### Carcinogenicity

Based on available data the classification criteria are not met.

### Reproductive toxicity

Based on available data the classification criteria are not met.

# Toxicity for specific target organ - single exposure

Based on available data the classification criteria are not met.

## Toxicity for specific target organ - repeated exposure

Based on available data the classification criteria are not met.

# **Aspiration hazard**

Based on available data the classification criteria are not met.

### **SECTION 12: Ecological information**

# 12.1. Toxicity

not available

# **Acute toxicity**

sodium azide						
Parameter	Value	Exposure time	Species	Environment		
EC50	5.6 mg/l	48 hours	Aquatic invertebrates			

# 12.2. Persistence and degradability

not available

# 12.3. Bioaccumulative potential

Not available.

# 12.4. Mobility in soil

according to Regulation (EC) No 1907/2006 (REACH) as amended

# Monoclonal or polyclonal antibodies, proteins (including lyophilized)

Creation date 21st July 2023 Revision no.

Revision date Version 1

Not available.

#### 12.5. Results of PBT and vPvB assessment

Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of Regulation (EC) No 1907/2006 (REACH) as amended.

#### 12.6. Other adverse effects

Not available.

#### **SECTION 13: Disposal considerations**

#### 13.1. Waste treatment methods

Hazard of environmental contamination; dispose of the waste in accordance with the local and/or national regulations. Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed of with municipal waste. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

# Waste management legislation

Producer Responsibility Obligations (Packaging Waste) Regulations 2007 (S.I. No. 871 of 2007). Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended. Decision 2000/532/EC establishing a list of wastes, as amended.

## **SECTION 14: Transport information**

#### 14.1. UN number

not subject to transport regulations

#### 14.2. UN proper shipping name

not relevant

# 14.3. Transport hazard class(es)

not relevant

# 14.4. Packing group

not relevant

### 14.5. Environmental hazards

not relevant

# 14.6. Special precautions for user

Reference in the Sections 4 to 8.

## 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

not relevant

#### **SECTION 15: Regulatory information**

# 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Clean Air Act 1993 as amended. The Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 as amended. Public health act 1961. Environmental Protection Act 1990 as amended. Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

# 15.2. Chemical safety assessment

not available

# **SECTION 16: Other information**

# A list of standard risk phrases used in the safety data sheet

H310 Fatal in contact with skin.

according to Regulation (EC) No 1907/2006 (REACH) as amended

# Monoclonal or polyclonal antibodies, proteins (including lyophilized)

Creation date 21st July 2023 Revision no.
Revision date Version

H373 May cause damage to organs through prolonged or repeated exposure if swallowed.

1

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

H300+H330 Fatal if swallowed or if inhaled.

A list of additional standard phrases used in the safety data sheet
EUH032 Contact with acids liberates very toxic gas.

# Other important information about human health protection

The product must not be - unless specifically approved by the manufacturer/importer - used for purposes other than as per the Section 1. The user is responsible for adherence to all related health protection regulations.

### Key to abbreviations and acronyms used in the safety data sheet

ADR European agreement concerning the international carriage of dangerous goods by

road

BCF Bioconcentration Factor
CAS Chemical Abstracts Service

CLP Regulation (EC) No 1272/2008 on classification, labelling and packaging of

substance and mixtures

EC Identification code for each substance listed in EINECS

EC50 Concentration of a substance when it is affected 50% of the population EINECS European Inventory of Existing Commercial Chemical Substances

EmS Emergency plan EU European Union

EuPCS European Product Categorisation System IATA International Air Transport Association

IBC International Code For The Construction And Equipment of Ships Carrying

**Dangerous Chemicals** 

ICAO International Civil Aviation Organization IMDG International Maritime Dangerous Goods

INCI International Nomenclature of Cosmetic Ingredients
ISO International Organization for Standardization
IUPAC International Union of Pure and Applied Chemistry

LC50 Lethal concentration of a substance in which it can be expected death of 50% of the

population

LD50 Lethal dose of a substance in which it can be expected death of 50% of the

population

log Kow Octanol-water partition coefficient

MARPOL International Convention for the Prevention of Pollution from Ships

OEL Occupational Exposure Limits

PBT Persistent, Bioaccumulative and Toxic

ppm Parts per million

REACH Registration, Evaluation, Authorisation and Restriction of Chemicals

RID Agreement on the transport of dangerous goods by rail

UN Four-figure identification number of the substance or article taken from the UN

Model Regulations

UVCB Substances of unknown or variable composition, complex reaction products or

biological materials

VOC Volatile organic compounds

vPvB Very Persistent and very Bioaccumulative

Acute Tox. Acute toxicity

Aquatic Acute Hazardous to the aquatic environment

Aquatic Chronic Hazardous to the aquatic environment (chronic)
STOT RE Specific target organ toxicity - repeated exposure

## **Training guidelines**

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

### Recommended restrictions of use

according to Regulation (EC) No 1907/2006 (REACH) as amended

# Monoclonal or polyclonal antibodies, proteins (including lyophilized)

Creation date 21st July 2023 Revision no.
Revision date Version

Version 1

not available

# Information about data sources used to compile the Safety Data Sheet

REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

# The changes (which information has been added, deleted or modified)

The first edition of the GB version of the safety data sheet.

#### More information

Classification procedure - calculation method.

# **Statement**

The safety data sheet provides information aimed at ensuring safety and health protection at work and environmental protection. The provided information corresponds to the current status of knowledge and experience and complies with valid legal regulations. The information should not be understood as guaranteeing the suitability and usability of the product for a particular application.